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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,330	07/30/2003	Peter P. Antich	UTSW:1041	8756

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,330	ANTICH ET AL.	
	Examiner	Art Unit	
	Jaworski Francis J.	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 36 - 89 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 63-86 and 89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36 - 62 and 87 - 88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36 – 62 and 87-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) With respect to base claim 36, the language “ the transmitter “ and “ the processor “ lacks antecedence with the prior ‘ at least one ‘ terminology.

[Hence, inter alia the insertion of these latter terminologies before the terms in quotes and a carry forward of consistency throughout the dependent claims would obviate this portion of the rejection.]

2) The language “ is concentric “ is vague insofar as it is ambivalently interpretable absent the addition thereafter for example of -- with (the emission path) -- thereafter.

[Alternately stated and for visualization purposes, in applicants' Fig. 2 the receiver elements 16i and 16h may be said to be concentric about a line through their common focal point which bisects the angle between these two receiver elements. Or this may pertain to the condition of being concentric about the emission path of the transmitter to the focal point. Or it may pertain to the concentricity of the nested 'cylinder' surfaces defined by the two arrays in Fig. 1. The point is that any and all pairs of two points in space are 'concentric' absent a definition of what the concentricity

means. Further, when 'at least one transmitter' is construed to mean plural transmitters then the meaning murky further in the current wording.

One avenue to obviate this portion of the rejection and without regard to other effective languages would be to define that the one or more transmitters and one or more receivers serve to define respective emission surfaces which are generally concentric about the focal point (generally accommodating that small transducer elements may accomplish this purpose while being flat in their emission faces).]

3) It is unclear how the three differing terminologies representing the investigated region, the 'focal point', the '(cortical and trabecular) bone', and the 'target' are related to each other.

This portion of the rejection may be obviated by inter alia a recitation that the structural relationship is extant when the focal point is positioned so as to target a location in or on the bone (albeit the human body cannot be claimed within the structure combination). The examiner is cognizant that multiple such focal points/targets/bone locations are investigated to complete an examination per spec page 9 lines 25 – 29 such that a focal point may pertain to one site on a target or bone being investigated and so forth in the sense of unit versus whole.

4) The language "each angle" and "the critical angles" lacks antecedence with the antecedent "separated by an angle" language.

[Alternately stated, the initial use of the term 'angle' (singular) is interpretable to generically pertain to i) the geometric relationship of the receivers to each other or to the 'at least one transmitter' (see issue 2) above), or ii) a relationship existing at one

investigated angle from among the angles simultaneously investigated and that yields a unit datum, as well as iii) the integrated structure interaction that yields the data from plural angles for example of spec para [0020] step "e)" alone or together with "f)". The later terminologies in quotes above however pertains inferentially only to iii), that is, structural interaction associated with multiple angles.

Another way to state the ambiguity is that the receiver and processor portions of the claim have a disjuncture therebetween. In the receiver portion "simultaneously" in its context is not only inferential of the measurement at different angles necessary to obtain the cortical and trabecular critical angles which is performed concurrently under one advantage of applicants' invention but may simply pertain to an extended focal zone (since these are football-shaped regions) which grazes both regions. So this term in and of itself is insufficient to tie the claim together and resolve the angle/angles inconsistency in the latter portion of the claim.

A resolving suggestion on this portion of the rejection is not being proffered by the examiner because it relates to the core scope of claiming which applicants intend.

5) Additionally the language change "detects" to -- is adapted to detect -- is sought.

6) Additionally the preamble is directed to the transducer subcombination and the body of the claim to the combination of transducer and processor.

[This may be remedied by inter alia preamble claiming of a device comprising the two as its elements.]

With respect to claim 50, issues 1), 2), 3) and 5) apply and also “ the receivers ” lacks strict correspondence with the antecedent “ receiver array” terminology.

Additionally since the human body cannot be inferentially claimed, suggest change “ the focal point is “ to -- when the focal point is targeted to be -- or an equivalent.

Additionally, “ the transducer “ lacks antecedence. An initial definition of a transducer assembly which comprises the at least one transmitter and the receiver array would obviate this issue..

Additionally line last suggest change “ calculates “ to -- calculate -- and before “ bone “ add -- region of said --.

Dependent claims variously inherit the base claim defects and should be reviewed for inconsistencies with the base claims and any revisions thereto.

With respect to claims 87 – 88, i) the claims recite no active steps and additionally ii) the claims do not relate maximum and minimum elasticity coefficients and anisotropy determination to the recited uses within the apparatus base claims from which they depend, these uses being for the determination of critical angles or cortical and trabecular bone.

[Alternately stated, it is as it were that respective claims 49 and 62 were pre-supposed in antecedence to bridge the disjuncture.]

Additionally with respect to claim 87 after “transducer” -- and processor – should be added, or whatever overarching preamble noun is selected in resolving issue 6) supra.

The examiner’s understanding of how the system functions is that exemplarily six different measurements are taken in different orientations determined by rotating about the omega and phi angles of Fig. 5 at a test site, each being of a critical cortical and trabecular angle determined in turn by simultaneous operation of the transmitter receiver array assembly concentrically nested about the focal point, each such critical angle being in reference to a normal to the bone (determined automatically for example prior to the taking of the first of the six measurements), the measurement set being taken for exemplarily three such sites along a target bone, and using the critical angle determinations the maximum and minimum elasticity coefficients are determined, a max/min ratio is formed, and then in relation to how this max/min ratio of the elasticity coefficients is determined an anisotropy result is achieved which serves as an index of bone quality. Since the inventors are the best repository of understanding as to whether this characterization is verbatim accurate the examiner would defer to a refinement of understanding provided by counsel.

The point is that the examiner is requesting that for clarity in accordance with the statute a severality of generic steps be provided:

1) a step of using the transducer/device (if claim 36 amended re issue 6) above)/reflectometer as defined in claim 36(50) to effect a critical angle measurement on cortical and trabecular bone, and

2) a step of simultaneously deriving the maximum and minimum elasticity coefficients from the said critical angle measurement, and (in the same claim or in a new dependent claim)

3) A step of repeating steps 1) and 2) in a variety of orientations to determine bone anisotropy using the said derived maximum and minimum elasticity coefficients.

Patentability Assessment

No rejection is provided on art, and only issues of clear and definiteness of claiming remain.

The examiner is fronting a set of suggestions towards resolving claims indefinitenesses re claims 36 and 50, however with respect to the core issue 4) in the apparatus claims regarding how best to recite the inventive advantage regarding simultaneity and multiple investigative angles the examiner is deferring to counsel and applicants, and again with respect to a fully accurate method claims narration of the hierarchy and progression from determination of a normal, determination of a critical angle, determination of max/min elasticity coefficients, determination of anisotropy in the context of the simultaneities and angulations and temporal progression for these determination at one or more sites the examiner is again deferring to counsel and the applicants for accurate wordings claiming this technology consistent with their disclosure.

Moilanen et al (US2005/0004457, of record with applicants' IDS) was considered for its angulated transducer assembly apparatus of Figures 10 – 12, however this

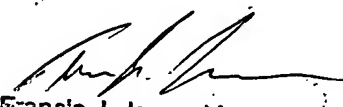
Art Unit: 3768

apparatus is used to produce mode conversion and guided wave propagation along the bone which together with for example an attenuation measurement is passed through an inversion or neural network in order to obtain elastic constants for the bone, as opposed to critical angle measurement. Anisotropy is determined by varying the assembly orientation but dispersion measurement is used as the intermediate.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

3-17-07



Francis J. Jaworski
Primary Examiner